DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2015

K.M.S. Inc.
c/o Mr. Charlie Mack
International Regulatory Consulting
12226 Washington Lane
Parker, Arizona 85344

Re: K142920
Trade/Device Name: KM Needles (Acupuncture Needle)
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: April 29, 2015
Received: May 06, 2015

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142920

Device Name
KM Needles (Acupuncture Needle)

Indications for Use *(Describe)*
This KM Needles (Acupuncture Needle) is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the state regulations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May 29, 2015
510(k) Number: K142920

1. Company and Correspondent making the submission:

Name – K.M.S Inc.
Address – F2, 81-1 Haengjeong-ri, Gwangdeok-myeon, Dongnam-gu, Cheonan-si, Chungcheongnam-do, Korea 330922
Tel: 82-41-5587785
Fax: 82-41-5587786
Contact – Mr. Chul Hui.Kim
Executive Director
Email – charliemack@irc-us.com

2. Device :

Trade/proprietary name: KM Needles (Acupuncture Needle)
Common Name : Acupuncture Needle
Classification Name : needle, acupuncture, single use

3. Predicate Devices :

Dong Bang Acupuncture Needles, (K972659)

4. Classifications Names & Citations :

21CFR 880.5580, MQX, Acupuncture Needle, Class 2

5. Description :

The KM Needles (Acupuncture Needle) are simple stainless steel pins that are used by an acupuncture practioner in the treatment of various conditions. Acupuncture is the timulation of specific acupuncture points along the skin of the body involving various methods such as penetration by thin needles or the application of heat, pressure, or laser light. Clinical practice varies depending on the country. Traditional acupuncture involves needle insertion, moxibustion, and cupping therapy. It is a form of alternative medicine and a key component of traditional Chinese medicine (TCM).

The KM Needles (Acupuncture Needle) are constructed of stainless steel, with pin body diameters ranging from 0.16 to 0.70 mm and vary in length from 15 to 135 mm. Each acupuncture needle has a handle for the practioner to manipulate the needle. The handle is also made from stainless steel and range in length from 20-30 mm.

6. Indication for use :
This acupuncture needle is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the state regulations.

7. Comparison with predicate device :
K.M.S Inc. believes that the KM Needles (Acupuncture Needle) is substantially equivalent to the Dong Bang Acupuncture Needles (K972659).

The predicate device chosen is comprised of the same material and both are single use devices delivered in a sterile condition. The predicate uses EO as the sterilization method and the KM Needles (Acupuncture Needle) are sterilized using radiation. Please note the table below, which demonstrates the similarities of the K.M.S Inc. Acupuncture Needles and the predicate device.

The table provides a comparison of the KM Needles (Acupuncture Needle) with the predicate device:

Element of comparison	**Subject Device**	**Claimed SE Device**
Company	K.M.S Inc.	Dong Bang Acupuncture Needle
FDA510(K) Number	N/A	K972659
Device Name	KM Needles (Acupuncture Needle)	ACUPUNCTURE NEEDLES
Intended Use	This acupuncture needle is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the state regulations.	This acupuncture needle is intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
Principle of operation	General and hand type	General and hand type
Material: - Needle body - Handle	STS 304	STS 304
Specification: - Length - Diameter	Length: 15~135mm Diameter: 0.16~0.70mm	Length: 7~150mm Diameter: 0.16~0.50mm
Tensile Strength of the Acupuncture Needle	Diameter : 0.20 (723.3gf) 0.25 (726.6gf) 0.35 (733.3gf)	Diameter : 0.20 (709.6gf) 0.25 (673.6gf) 0.35 (686.3gf)
Biocompatibility	Conform to ISO10993-1	Conform to ISO10993-1
Design	Spring	Spring
Reuse	Disposable, single use	Disposable, single use
Sterility	Gamma radiation	Sterilized by EO; SAL=10-6

The submitted K.M.S Inc. device and the predicate device have undergone testing to validate the tensile strength of the materials and also testing to verify the sterilization process and the sterile properties of the device, as delivered. The testing performed demonstrated that the devices met all of the criteria in these standards and that the submitted devices are similar in construction and delivered in the same state as the predicate Dong Bang acupuncture needles.

8. Performance Data :

Bench testing was performed to ensure the tensile strength of the stainless steel needle and Sterility testing (ISO10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process; ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, ISO 1137-2 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose, AAMI/ISO/ANSI 11737-1 Sterilization of medical devices - Microbiological methods Part 1: Determination of the population of microorganisms on product, 2ed, AAMI ANSI ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, AAMI ANSI ISO 11607-2 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.) was performed. All test results were satisfactory.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification K.M.S Inc. concludes that the KM Needles (Acupuncture Needle) are as safe and effective and substantially equivalent to predicate devices as described herein.

END